Filed Jan. 23, 1968. Nathan J. Paulson, Clerk

UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 20,709

THE ELMO COMPANY, INC., a corporation, *Petitioner*,

v.

FEDERAL TRADE COMMISSION, *Respondent*.

FINAL DECREE AFFIRMING ORDER OF THE FEDERAL TRADE COMMISSION SETTING ASIDE PRIOR CONSENT SETTLEMENT AND ORDER.

Before: BAZELON, Chief Judge; FAHY, Senior Circuit Judge; BURGER, Circuit Judge.

The Elmo Company, Inc., a corporation, petitioner herein, having filed in this Court on January 16, 1967, a petition to review and set aside an order of respondent Federal Trade Commission setting aside a prior consent settlement and order (but staying the effective date of such setting aside until a new superseding order of the Commission shall take effect), issued on November 18, 1966, in a proceeding entitled In the Matter of The Elmo Company, Inc., a corporation, Docket No. 5959; and the matter having been heard by this Court on the record and briefs on September 13, 1967; and this Court having on December 27, 1967, issued its opinion affirming the order of respondent Federal Trade Commission;

NOW, THEREFORE, IT IS ORDERED, ADJUDGED AND DECREED by the Court that the order of respondent Federal Trade Commission setting aside prior consent settlement and order, but staying the effective date of such setting aside until a new superseding order shall take effect, is hereby affirmed.

By the Court.

DAVID L. BAZELON,
Chief Judge.

CHARLES FAHY,
Senior Circuit Judge.

WARREN E. BURGER,
Circuit Judge.

UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 20,709

THE ELMO COMPANY, INC., *Petitioner,*

v.

FEDERAL TRADE COMMISSION, *Respondent.*

Petition for Review of Order of the Federal Trade Commission

Decided December 27, 1967

Mr. Geo. Stephen Leonard for petitioner.

Mr. Daniel H. Hanscom, Attorney, Federal Trade Commission, with whom *Mr. James McI Henderson,* General Counsel, Federal Trade Commission, was on the brief, for respondent. *Mr. Harold Rhynedance, Jr.,* Attorney, Federal Trade Commission, also entered an appearance for respondent.

Before BAZELON, *Chief Judge,* FAHY, *Senior Circuit Judge,* and BURGER, *Circuit Judge.*

BURGER, *Circuit Judge:* In 1952 the Federal Trade Commission issued a complaint against the Elmo Corporation for engaging in false and deceptive practices in marketing a series of products known as the "Elmo Palliative Home Treatment." A consent decree resulted which permitted Elmo to claim that its products had some beneficial effects in the treatment of impaired hearing or head or ear noises. Elmo revised its advertising subsequent to this order. Since that time, advertising has been primarily by way of user endorsements, claiming beneficial effects for this treatment in their own cases.

In 1964 the Commission filed a new complaint for deceptive advertising, this time against the Drive-X Company, Inc., which had purchased the treatment in 1961 from Elmo. The Drive-X Company sued in the District Court to enjoin that complaint and to require the Commission to proceed by reopening the prior order. The District Court dismissed for want of jurisdiction. On appeal, this Court

found the District Court to have jurisdiction to so direct the Commission. *Elmo Division of Drive-X Company* v. *Dixon*, 121 U.S. App. D.C. 113, 348 F. 2d 342 (1965). The Court did not rely solely on the statutory provision for rehearing to reopen a prior order,[1] but pointed to the rule of the Commission entitling petitioner to a hearing on a proceeding to re-open the consent order that was incorporated into the 1952 order as creating a "plain statutory command" that such a proceeding be followed.

The Commission then re-opened the 1952 order. A hearing examiner held hearings at which the Commission and petitioner were represented by counsel who presented briefs, proposed findings and oral arguments. Each side also presented the written statements, in question and answer form, of three experts relating to the effectiveness of the "Elmo Palliative Home Treatment." The experts for the Commission, although none of them had tested the Elmo treatment, stated that its stipulated ingredients could have no beneficial effects on the loss of hearing or head noises. The experts for petitioner stated that, although the ingredients of the Elmo treatment have been supplanted by modern drugs as the most effective treatment, they do have some beneficial effects on head noises and loss of hearing, and some doctors still recommend these ingredients. Petitioner also presented fourteen texts on otolaryngology and pharmacology to support the claimed beneficial effects of the ingredients of its products.

After setting out most of the statements of the Commission experts, the hearing examiner's recommendation to the Commission stated that the medical testimony showed sufficient reason to believe that the public interest would be served by setting aside that part of the prior order permitting the claim of some benefits from petitioner's treatments.[2]

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[1] 15 U.S.C. § 45(b) (1964).

[2] The hearing examiner concluded:

> One quarter of a million people have already paid respondent either the first asking price of $10 or the follow-up price of $7.35 for the "Elmo Palliative Home Treatment." Unless the 1952 consent settlement be set aside in part and corrective action undertaken consistent

The Commission then received briefs and heard oral arguments on the question of re-opening the 1952 order. It found that "the 1952 order fails adequately to protect the public interest" and decided that the entire 1952 order should be re-opened, staying the effect of the re-opening until a superseding order should become effective. This is now under review.

The only substantial question raised by this appeal is what showing of public interest is necessary to re-open a final order of the Federal Trade Commission.[3] Although the present hearing was apparently pursuant to the terms of the consent order itself, *Elmo Division of Drive-X Company* v. *Dixon*, 121 U.S. App. D.C. 113, 116, 348 F. 2d 342, 345 (1965), we can see no distinction now regarding the standards to re-open between this hearing and one under § 5(b) of the Federal Trade Commission Act, 15 U.S.C. § 45(b) (1964).

The thrust of petitioner's argument is that the finding of "public interest" as a basis to re-open must be greater than that necessary to bring a complaint in the first place. Petitioner relies on three cases for this proposition: *Civil Aeronautics Board* v. *Delta Air Lines, Inc.*, 367 U.S. 316 (1961); *American Trucking Ass'ns, Inc.* v. *Frisco Transportation Company*, 358 U.S. 133 (1958); *United States* v. *Seatrain Lines, Inc.*, 329 U.S. 424 (1947). None of these cases gives direct support to petitioner. *Delta* merely held the CAB to the statutory requirement of notice and a hearing if it was to revoke a certificate of convenience and necessity. *American Trucking* permitted the ICC to open an order to correct an inadvertent, clerical error. And *Seatrain* held that the ICC could not partially revoke a certificate of convenience and necessity for a water carrier when Congress had not granted this power.

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with the preceding findings herein made, a considerable number of the purchasing public may further go unprotected and suffer substantial monetary loss in the payment for a treatment described on the record of this hearing by qualified and experienced specialists, as worthless for the represented results advertised.

[3] The Commission relies on the "public interest" basis because the findings of the trial examiner did not show any change of fact or law—the other bases for re-opening an order under both the 1952 order and the statute, 15 U.S.C. § 45(b) (1964).

More in point is the decision of the Ninth Circuit in *Mohr* v. *Federal Trade Commission*, 272 F. 2d 401 (9th Cir. 1959). There, as here, the Commission re-opened a prior order. The new order required affirmative disclosure that the forms in question were seeking information to locate delinquent debtors, whereas the original order merely prohibited any representation that the forms were for other purposes. The Court held that, even if the first order had been intended to require affirmative disclosure, "ineptness of expression in the original order would not stand in the way of reopening and modifying the order." 272 F. 2d at 405. Alternatively, if the Commission had since decided that affirmative disclosure was necessary, "this would likewise be immaterial. Experience under the cease and desist order . . . showed that mere elimination of specific statements from the forms was not enough to stop the deception. The Commission was entitled to change its mind, if that is what it has done, as to the kind of a cease and desist order which was necessary to protect the public interest." 272 F. 2d at 405-06. Clearly, the Court was looking to public interest at the time that the order was re-opened. There is nothing to suggest that it was referring to a different standard than it would use to test the public interest in issuing a new complaint.

The premise from which we approach this question is that "the Commission is not a private party, but a body charged with the protection of the public interest; and it is unthinkable that the public interest should be allowed to suffer as a result of inadvertence or mistake on the part of the Commission or its counsel where this can be avoided." *P. Lorillard Co.* v. *Federal Trade Commission*, 186 F. 2d 52, 55 (4th Cir. 1950). Where the statute expressly permits reopening of an order if the public interest requires, we see no reason to employ a higher standard of public interest than in that part of the same section of the statute relating to the issuance of an initial complaint.[4]

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[4] 15 U.S.C. § 45(b) (1964). The public interest to initiate a complaint must be "specific and substantial." See Federal Trade Commission v. Royal Milling Co., 288 U.S. 212 (1933); Federal Trade Commission v. Raladom Co., 283 U.S. 643 (1931).

The function of the Commission is essentially the same in both instances.

The Commission makes a sufficient showing to re-open a prior order if it shows reasonable grounds to believe that the public interest at the present time would be served by the re-opening. Such a showing has been made here. The Commission's experts raised a serious question as to whether petitioner's treatment has any beneficial effects at all. Petitioner has advertised the product to have beneficial effects and there are substantial sales.[5] Consequently, the Commission's finding that the public interest warrants re-opening the 1952 consent order should be affirmed.

Affirmed.

[5] See footnote 2 *supra*.

UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 20,709

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v.

FEDERAL TRADE COMMISSION, *Respondent.*

PREHEARING CONFERENCE STIPULATION

Counsel for the parties have met on several occasions and have reached an agreement on stipulation of issues.

The parties accept as true for the purposes of this appeal the findings listed in numbered paragraphs 1, 2, and 3 appearing in the Commission's summarized statement of reasons for its decision, as given in its opinion herein, and raise as the sole issue before this Court the legal adequacy of the conclusion set forth in paragraph 4 thereof. The four paragraphs referred to read as follows:

"1. The order issued in 1952 and now in effect permits respondent to represent that the use of its preparation and device will have some beneficial effect in the treatment of deafness, impaired hearing, or head or ear noises.

"2. The medical testimony in the record, summarized in Finding 10 at pages 9-17, supports the conclusion that the preparations and devices comprising the Elmo Palliative Home Treatment have no beneficial effect whatsoever in the treatment of poor hearing, deafness, and head or ear noises.

"3. Respondent's current advertising represents that its product will relieve poor hearing and head or ear noises.

"4. On the basis of the foregoing, we conclude that the 1952 order fails adequately to protect the public interest."

The parties stipulate that the briefs shall be exchanged in typewritten form on the dates on which they are due and

that briefs and the joint appendix in printed form will be filed by the date on which the reply is due.

GEO. STEPHEN LEONARD,
Counsel for Appellant.

DANIEL H. HANSCOM,
Counsel for Respondent.

March 1, 1967.

Prehearing Order

Counsel for the parties in the above-entitled case having submitted their stipulation pursuant to Rule 38(k) of the General Rules of this Court, and the stipulation having been considered, the stipulation is approved, and it is

Ordered that the stipulation shall control further proceedings in this case unless modified by further order of this court, and that the stipulation and this order shall be printed in the joint appendix herein.

ORDER SETTING ASIDE CONSENT SETTLEMENT AND ORDER

The Commission having issued on December 1, 1965, its "Order Vacating Order To Show Cause And Reopening Proceeding To Determine Whether A Change Of Law Or Fact Or The Public Interest Requires Setting Aside Consent Settlement In Whole Or In Part", and a hearing before an examiner having been held pursuant to that order; and

The Commission having considered the evidence introduced by the parties at the hearing, the proposed findings and conclusions submitted by the parties, the briefs in support thereof, and having heard oral argument; and

The Commission having determined, for the reasons set forth in its opinion accompanying this order, that such action is now required in the public interest:

IT IS ORDERED that the consent settlement and order entered herein on June 10, 1952, be, and they hereby are, set aside in whole.

IT IS FURTHER ORDERED that this order shall not take effect until such time as a new order of the Commission fully disposing of the complaint in Docket No. 5959, in its present form or as it may be amended, and superseding the consent settlement and order entered herein on June 10, 1952, shall become final.

By the Commission.

JOSEPH W. SHEA,
Secretary.

(SEAL)

ISSUED: November 18, 1966

OPINION OF THE COMMISSION

By Commissioner Elman:

This case concerns the reopening and modification of Commission orders to cease and desist. Such orders, like judicial injunctions are not immutable. "A continuing decree of injunction directed to events to come is subject always to adaptation as events may shape the need." *United States* v. *Swift & Co.*, 286 U.S. 106, 114. With respect to Commission orders that have become final, whether by consent or after litigation, Section 5(b) of the Federal Trade Commission Act provides that "the Commission may at any time, after notice and opportunity for hearing, reopen and alter, modify, or set aside, in whole or in part, any report or order made or issued by it under this section, whenever in the opinion of the Commission conditions of fact or of law have so changed as to require such action or if the public interest shall so require." Cf. *American Chain & Cable Co., Inc.* v. *Federal Trade Commission*, 142 F. 2d 909, 911 (4th Cir.).

Under the present practice (Section 3.28, Rules of Practice), the Commission, acting on its own motion or at the request of a party, may reopen a proceeding for the purpose of modifying or vacating an outstanding order. In the absence of consent to the proposed modification or vacation of the order, and where substantial issues of fact are involved, the matter is heard initially before a hearing examiner, and then before the Commission, to determine whether and how the order should be altered. Normally, the question whether, by reason of changed conditions or the public interest, the outstanding order should be vacated is intertwined with the question of determining the terms of a new superseding order to be entered. Under the present practice, the Commission enters, a single new order determining both of these related questions which is, of course, subject to judicial review in the same manner as other Commission orders.

In the instant case, however, we are obliged by the decision of the Court of Appeals for the District of Columbia Circuit in *The Elmo Division of Drive-X Company* v. *Dixon*,

348 F.2d 342 (1965),[1] to consider and decide separately the question whether the existing order should be set aside, before taking up the question of the content and scope of a new superseding order. The Court of Appeals upheld respondent's contention that the Commission had bound itself, by entering into the agreement upon the basis of which the consent order in this case was issued on June 10, 1952, to follow the procedure prescribed by Rule V(f) of the Commission's Rules in effect at that time, which was construed by the Court of Appeals to require the Commission to enter a separate order (which would be judicially reviewable immediately) setting aside the old consent order as a prerequisite to reopening the proceeding for the purpose of issuing a new modified order.

We have scrupulously followed the course required by the mandate of the Court of Appeals. On December 1, 1965, after the case was remanded to us, the Commission issued an order reopening the proceeding in Docket 5959 to determine whether a change of law or fact or the public interest required setting aside, in whole or in part, the consent order issued in 1952. The matter was assigned to a hearing examiner with instructions to take evidence to determine whether changed conditions or the public interest requires that the order be so set aside, and to certify the record, together with a report of his findings, conclusions, and recommendations, to the Commission for final disposition. The hearing before the examiner having been held, the matter is now before the Commission on the examiner's certification of the record.

The only question before the Commission in the present posture of the case, we repeat, is simply whether the outstanding 1952 consent order should be vacated in whole or in part, and not what the terms or scope of a new superseding order should be. Because of the unusual manner in which we have been directed to proceed in this case, the Commission intimates no view whatsoever on the latter question. We have determined only, for the reasons shortly to be stated, that the findings of fact and conclusions of law

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[1] Since this case was regarded as *sui generis* and having no general precedential importance, certiorari was not sought.

contained in the hearing examiner's certification are correct and valid; and, with one modification, they are hereby adopted by the Commission as its own. We find and hold that the public interest requires that the consent order issued by the Commission on June 10, 1952, be reopened and set aside in whole, rather than in part as recommended by the examiner. We are this date entering an order to that effect. Under the decision of the Court of Appeals in this case, respondent will have the opportunity it successfully sought of obtaining immediate judicial review. If and when today's order vacating the 1952 consent order should become final, because respondent does not seek court review or because upon such review our order should be affirmed, the Commission will promptly initiate such further administrative proceedings as are found to be warranted by the then existing circumstances.

The reasons for our determination to vacate in its entirety the consent order issued in 1952 may be summarized as follows:

1. The order issued in 1952 and now in effect permits respondent to represent that the use of its preparation and device will have some beneficial effect in the treatment of deafness, impaired hearing, or head or ear noises.

2. The medical testimony in the record, summarized in Finding 10 at pages 9-17, supports the conclusion that the preparations and devices comprising the Elmo Palliative Home Treatment have no beneficial effect whatsoever in the treatment of poor hearing, deafness, and head or ear noises.

3. Respondent's current advertising represent that its products will relieve poor hearing and head or ear noises.

4. On the basis of the foregoing, we conclude that the 1952 order fails adequately to protect the public interest.

Accordingly, the Commission's duty to safeguard the public interest requires that the consent settlement and order entered herein on June 10, 1952, be set aside in whole. In order to prevent a hiatus in which respondent would be entirely free from *any* order, we are staying the effective date of today's order until such time as a new superseding

order of the Commission, finally disposing of this complaint, shall take effect. Respondent may thus obtain immediate judicial review of our present order, without the harm to the public interest which would result if it were wholly relieved from the prohibitions of any order during the pendency of judicial review.

Complaint counsel's motion to strike the reply brief filed by respondent is denied.

November 18, 1966

CERTIFICATION OF RECORD WITH FINDINGS OF FACT, CONCLUSIONS AND RECOMMENDATIONS THEREON IN CONFORMANCE WITH COMMISSION'S REOPENING ORDER OF DECEMBER 1, 1965.

History of the Proceeding

Complaint issued against the above respondent on February 28, 1952, charging violation of the Federal Trade Commission Act in the interstate advertising, sale and distribution of drug preparations and devices for treatment of disorders of the human ear. Respondent, prior to hearing, entered into a consent settlement containing a cease and desist order which was accepted by Commission order on June 10, 1952. Paragraph 3, page 2 of the consent settlement provides it may be set aside, in whole or in part, under the conditions and in the manner provided in paragraph (f) of Rule V of the Rules of Practice then in effect.[1] The requirements of paragraph (f) of Rule V in the consent settlement are spelled out in the February 11, 1965, opinion of the United States Court of Appeals for the District of Columbia Circuit in *The Elmo Division of Drive-X Company, Inc., et al.* v. *Federal Trade Commission*, 348 F.2d 342.

The docket file shows that on September 16, 1965, the Commission entered an order herein entitled Order To Show Cause Why Proceeding Should Not Be Reopened

[1] The rule in effect at the time of the consent settlement reads as follows: "(f) Pursuant to a change of law or facts, or when the public interest so requires, a consent settlement may be altered, modified, or set aside, in whole or in part, upon consent of all parties. All consent settlements shall contain an agreement that if consent to a change desired is not obtained, the Commission or any respondent may file a motion in the case to set aside such consent settlement, in whole or in part, on the grounds of change of law or fact or that the public interest so requires; and after opportunity for hearing upon the issues formed, the Commission may, if it finds that a change of law or fact, or the public interest so requires, set aside the consent settlement or any part thereof which is separable from the remaining provisions without changing their effect. Thereafter, the Commission may, by adversary proceedings pursuant to the original complaint, or a new or amended and supplemental complaint, undertake corrective action as to any acts or practices not prohibited by any remaining provisions of the consent settlement."

which recited the 1952 consent settlement order to cease and desist, and directed, among other things, that the respondent may show cause why the public interest does not require (1) that the proceeding be reopened, (2) that the order of June 10, 1952, be vacated and set aside, (3) that the complaint be amended as per the amended complaint accompanying this order, (4) that after appropriate proceedings the order to cease and desist attached to the amended complaint be entered. The accompanying amended complaint provided for an order to cease and desist more restrictive than that contained in the consent settlement. This order to show cause was vacated by the Commission on December 1, 1965.

The foregoing vacating Commission order of December 1, 1965, is entitled Order Vacating Order To Show Cause and Reopening Proceeding To Determine Whether A Change Of Law Or Fact Or The Public Interest Requires Setting Aside Consent Settlement In Whole Or In Part. This reopening order refers the matter to a hearing examiner for the purpose of receiving evidence, provides that the proceeding be conducted pursuant to the Commission's Rules of Practice for Adjudicative Proceedings insofar as applicable, and directs that the hearing examiner upon the conclusion of the hearing certify the record, together with a report of his findings, conclusions and recommendations with respect thereto, to the Commission for disposition.

A stenographically reported prehearing conference was held herein on February 18 and March 18, followed by a brief hearing on April 18 and 19, 1966. The record consists of the complaint, the consent settlement and order to cease and desist, the instant Commission reopening order, the answer filed thereto by respondent, a record stipulation between respective counsel, Commission Exhibit No. 1 a bound indexed documentary exhibit, and Respondent's Exhibit Nos. 2 and 3 also bound indexed documentary exhibits.

Commission Exhibit No. 1 in evidence contains reproductions of respondent's magazine and newspaper advertisements, and followup literature sent by respondent to potential purchasers of the "Elmo Palliative Home Treat-

ment." Included in the exhibit is a listing of the professional qualifications and published works of three medical doctors and excerpts of the testimony they would give on direct examination if called as witnesses. Respondent's Exhibit No. 1 contains excerpts from the testimony on cross-examination which would be given by these Commission medical witnesses, as well as excerpts from the testimony which would be given on direct examination by respondent's three medical witnesses and their professional qualifications. Included in the exhibit are excerpts from the testimony on direct examination of one of respondent's officials and two lay users, of respondent's products if called as witnesses. Respondent's Exhibit No. 2 contains literature connected with claimed satisfactory use by various purchasers of the "Elmo Palliative Home Treatment", a listing of the published works and professional associations of its three medical witnesses, and extracts from various medical texts.[2]

Proposed findings of fact, conclusions and supporting briefs were filed by respective counsel and a stenographically reported oral argument was held before the hearing examiner on June 10, 1966. Proposed findings of fact and conclusions submitted and not adopted in substance or form as herein found and concluded are hereby rejected.

After carefully reviewing the entire record of this proceeding as hereinbefore described, it is hereby certified to the Commission in conformance with the reopening order herein of December 1, 1965, together with the following findings of fact, conclusions and recommendations for disposition by the Commission.

Findings of Fact

1. The Drive-X Company, Inc., trading as The Elmo Company, hereinafter referred to as "respondent" is a corporation organized, existing and doing business under

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[2] The evidentiary material contained in these exhibits was extracted from the record of testimony and exhibits in Docket No. 8615, *In the Matter of The Drive-X Company, Inc., et al., trading as The Elmo Company.* The initial decision in Docket No. 8615 was vacated on September 16, 1965, by the Commission's order therein entitled Order Dismissing Complaint In Part, Vacating Examiner's Initial Decision, and Suspending Proceedings.

and by virtue of the laws of the State of Iowa, with its principal office and place of business at Second and Main Streets, in the city of Madrid, in the State of Iowa. Respondent is successor in interest to The Elmo Company, Inc., a corporation formerly organized, existing and doing business under and by virtue of the laws of the State of Iowa with its principal place of business in Davenport, Iowa.[3]

The Drive-X Company, Inc., trading as The Elmo Company, the corporate successor to The Elmo Company, Inc., is bound by the order to cease and desist contained in the June 10, 1952 consent settlement in this proceeding in the same manner and to the same extent as its corporate predecessor, The Elmo Company, Inc.[4]

2. Respondent is now, and for some time last past, has been engaged in the sale and distribution of certain drug preparations and devices as the terms "drug" and "device" are defined in the Federal Trade Commission Act. The combination of the preparations and the devices is referred to by respondent as the "Elmo Palliative Home Treatment."

The designations and formulae used by respondent for its said preparations and the designation and description for said devices are as shown on pages 1387 through 1393 of the prior findings of fact in this matter (48 FTC 1379) with the addition of 20 pounds of sugar of milk to each 200 pounds of the formula for Elmo Nasal Cleaner No. 2. The directions for use of such preparations and the devices are as shown in Respondent' Exhibit No. 2.[5]

3. Respondent causes its said preparations and devices, when sold, to be transported from its place of business in the State of Iowa to purchasers thereof located in various other states in the United States and in the District of Columbia. Respondent maintains, and at all times mentioned herein has maintained, a course of trade in said preparations and devices in commerce, as "commerce" is

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[3] See paragraph 1 of record stipulation between counsel at Tr. 17-18.

[4] See paragraph 2, page 1 of answer filed by respondent on February 8, 1966, to the Commission's reopening order herein of December 1, 1965.

[5] See paragraph 2 of record stipulation between counsel at Tr. 18.

defined in the Federal Trade Commission Act. The volume of business in such commerce has been and is substantial.[6]

4. In the course and conduct of its business, respondent has disseminated, and caused the dissemination of, certain advertisements concerning its said preparations and devices by the United States mails and by various means in commerce, as "commerce" is defined in the Federal Trade Commission Act, including, but not limited to, advertisements inserted in newspapers, magazines, and by means of circulars and other advertising media, for the purpose of inducing and which were likely to induce, directly or indirectly, the purchase of said preparations and devices; and has disseminated, and caused the dissemination of, advertisements, of said preparations and devices, by various means, including, but not limited to, the aforesaid media, for the purpose of inducing and which are likely to induce, directly or indirectly, the purchase of said preparations and devices in commerce, as "commerce" is defined in the Federal Trade Commission Act.[7]

5. The unnumbered findings of fact and the conclusion in the 1952 consent settlement, entered into prior to a hearing in this proceeding, are but a reiteration of paragraphs one through twelve of the 1952 complaint issued against the respondent. The paragraph of the consent settlement findings as to the facts, permissive of certain representations in the consent settlement order to cease and desist now in effect in this proceeding, corresponds with the allegations of paragraph seven of the complaint and reads as follows:

> The said advertisements are misleading in material respects and constitute "false advertisements" as that term is defined in the Federal Trade Commission Act. In truth and in fact, the use of respondent's preparations, as directed or otherwise, will have no beneficial value whatsoever, in cases of deafness and impaired hearing except when caused by catarrh, that is, a chronic inflammation of, and hypersecretion from,

[6] See paragraph 3 of record stipulation between counsel at Tr. 18-19.

[7] See paragraphs 4 and 11 of record stipulation between counsel at Tr. 19 and 25.

the membranes of the nose, ear or air passages. When deafness or impaired hearing, together with ear or head noises, result from discharging catarrh, the use of respondent's preparations, as directed or otherwise, will have no beneficial effect in the treatment of said conditions in excess of temporarily relieving the catarrhal condition and the resulting deafness or impaired hearing and ear and head noises. In cases of deafness or impaired hearing and head and ear noises resulting from so-called dry catarrh, the benefits derived from the use of said preparations, as directed or otherwise, are limited to the softening of the dried exudates. Respondent's treatment would not usually result in the removal of these exudates from the ear canal and, until removed by other means, the deafness or impaired hearing and head and ear noises due to these exudates would be expected to continue. The use of Elmo No. 8 Ear-Vibrator, as directed or otherwise, will have no beneficial effect in the treatment of deafness or impaired hearing or of ear or head noises due to catarrh. Respondent's method of treatment and the preparations and device employed is not based on the findings of any accepted medical authorities. Catarrh is not the most common cause of deafness. Respondent's Elmo Ear Oil No. 1 and Elmo No. 8 Ear-Vibrator are not safe to use and may cause injury to the user as is more fully set out hereinafter.

The foregoing finding as to the facts in the consent settlement, as translated into the order to cease and desist in the consent settlement, has resulted in the following paragraphs now in effect in the said order to cease and desist:

(a) That the use of its preparations and device, singly or in combination, as directed or otherwise, will have any beneficial effect upon deafness not caused by a catarrhal condition of the nose, ear or air passages.

(b) That the use of its preparations and device, singly or in combination, as directed, or otherwise, will have any beneficial effect in the treatment of deafness, impaired hearing, or head or ear noises caused by dis-

charging catarrh, in excess of affording temporary relief therefrom.

(c) That the effects of its preparations in the treatment of deafness or impaired hearing or head or ear noises due to dry catarrh is in excess of softening of the dry exudates, or that any benefit can be expected by reason of this action of respondent's preparations in the treatment of conditions caused by dry catarrh of the ear canal unless the softened exudates are removed by other means.[8]

6. Subsequent to the consent settlement herein, respondent's advertising was revised in the alleged effort to conform with the various requirements of the order to cease and desist outstanding.[9] The revised advertising for respondent's products, disseminated as set forth in preceding finding number four, is as shown in Commission's Exhibit No. 1.[10] Typical of such advertising is the following:

"EAR NOISES relieved! . . . thousands reported. Wonderful relief from years of suffering from miserable ear noises and poor hearing caused by catarrhal (excess fluid mucus) conditions of the head! That's what these folks (many past 70) reported after using our simple Elmo Palliative HOME TREATMENT during the past 23 years. This may be the answer to your prayer. NOTHING TO WEAR. Here are SOME of the symptoms that may likely go with your catarrhal deafness and ear noises; Mucus dropping in throat. Head feels stopped up by mucus. Mucus in nose or throat every day. Hear —but don't understand words. Hear better on clear days—worse on bad days, or with a cold. Ear noises like crickets, bells, whistles, clicking or escaping steam or others, You, too, may enjoy wonderful relief if your poor hearing or ear noises are caused by catarrhal

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[8] The balance of the consent settlement order to cease and desist contains no permissive qualifications and further requires disclosures of possible harm to users of respondent's products.

[9] See paragraph 3, pages 1-2 of answer filed by respondent on February 8, 1966, to the Commission's reopening order herein of December 1, 1965.

[10] See paragraph 5 of record stipulation between counsel at Tr. 19.

conditions of the head and when the treatment is used as needed. Write now for PROOF of RELIEF & 30 DAY TRIAL OFFER. THE ELMO COMPANY, Dept. H25B Madrid, Iowa."

Respondent's advertising in the main is directed to the elderly, and the volume of respondent's business is substantial. The testimony of respondent's official, Craig W. Sandahl, in Respondent's Exhibit No. 1, at page 116 (f) and Commission's Exhibit No. 1, at pages 72-73 and 83-84, shows that respondent sends out about 15,000 treatments a year and that out of the number of people replying to respondent's advertisements over the past 30 years, approximately 60% or one quarter of a million people have paid respondent either respondent's first asking price of $10 or the follow-up price of $7.35.

People replying to respondent's advertising are sent reproduced follow-up testimonial letters [11] extolling respondent's treatment and making claims for its use, for example, as appears in one such letter: "Here I want to say I feel a complete cure." An examination by the hearing examiner [12] of these advertising and follow-up testimonial letter exhibits shows them plainly susceptible of being interpreted and understood by the purchasing public [13] as representing, directly or impliedly, that respondent's "Elmo Palliative Home Treatment" will have a beneficial effect on and cure or constitute an effective treatment for poor or lost hearing, ear and head noises, and so-called catarrhal conditions of the head.

7. Commission counsel in the absence of the present record stipulation would call the following witnesses: Dr.

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[11] Comm. Ex. No. 1, pages 63-68.

[12] See April 8, 1966, opinion of the Commission and cases therein cited, Docket No. 8635, *In the Matter of Merck & Co., Inc., et al.*, as to a finding based on such examination.

[13] "Advertisements are intended not 'to be carefully dissected with a dictionary at hand, but rather to produce an impression upon' prospective purchasers" and "the law is not made for experts but to protect the public—that vast multitude which includes the ignorant, the unthinking and the credulous, who in making purchases do not stop to analyze but too often are governed by appearances and general impressions." *Aronberg v. Federal Trade Commission*, 132 F. 2d 165, 167-168.

Donald F. Proctor, Dr. Samuel L. Fox and Dr. David Myers, whose qualifications, experience and publications are as shown in Commission's Exhibit No. 1.[14] The named witnesses if called by Commission counsel would testify under direct examination as shown in Commission's Exhibit No. 1.[15]

8. Counsel for respondent in the absence of the present record stipulation would call the following witnesses: Dr. McKeen Cattell, Dr. Benjamin Calesnick and Dr. Harry Cherken, whose qualifications, experience and publications are as shown in Respondent's Exhibit No. 2. In addition, respondent would call certain user witnesses.[16]

9. The foregoing named witnesses if called by counsel for respondent would testify under direct examination and the witnesses to be called by Commission counsel would testify on cross-examination as shown in Respondent's Exhibit No. 1.[17] In addition to the foregoing testimony, respondent would offer the exhibits from medical texts and other facts as shown in Respondent's Exhibit No. 2.[18]

10. The proffered testimony of respondent's official, Craig W. Sandahl, discloses that Respondent's business records show that the "Elmo Palliative Home Treatment" has been sold under the same formulae for approximately the past 30 years.[19] Commission's medical witness, Dr. Proctor would testify that he was familiar with the formulae of respondent's preparations and the devices used in the "Elmo Palliative Home Treatment", and further in part would state as follows:

> Q. Doctor, based on your scientific knowledge, training, research and experience and bearing in mind the quantitative formulae and the directions for use of the preparations and the devices comprising the Elmo

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[14] See paragraph 6 of record stipulation between counsel at Tr. 19.

[15] See paragraph 7 of record stipulation between counsel at Tr. 19-20.

[16] See paragraph 8 of record stipulation between counsel at Tr. 20. See also, *Merck & Co., Inc.*, and cases cited, footnote 11, supra, as to the necessity for and the probative weight to be given the testimony of these lay users of respondent's products.

[17] See paragraph 9 of record stipulation between counsel at Tr. 20.

[18] See paragraph 10 of record stipulation between counsel at Tr. 20.

[19] Resp. Ex. No. 1, pages 117-119.

Palliative Home Treatment, what is your opinion as to whether or not this product would be of value in curing catarrhal conditions of the head?

A. As I have said before, the term "catarrhal congestion of the head" is such a vague term that I do not think that any medical man would say that any particular thing would cure it. We would have to be more specific about it.

Q. Using the term "catarrhal" in the sense that it was used in the advertising as excess fluid mucus?

A. Well, I can answer, perhaps, in a general way by saying that as far as I know of my own personal knowledge, there is nothing in these treatments as described in the material that I have seen which I would expect to cure any condition related to the problem about which we have been talking.

Q. Would this opinion include poor hearing or ear noises caused by excess mucus?

A. It does, indeed, and an even more important consideration here is that, as I have already mentioned, there are some very serious disease processes which can cause these symptoms, such as the brain tumor or any number of things that I could mention, multiple sclerosis and so forth and so on, which might go undiagnosed if the patients were going through any long period of time with treatments such as this thing and he was not getting at the base of his trouble.

Q. What is your opinion as to whether or not this product would be of value as a cure for poor hearing or ear noises caused by any other condition other than excess fluid?

A. There is no condition that I know of that this would be of any use for.

Q. What is your opinion as to whether or not these products would be of value as an effective treatment for the relief of catarrhal conditions of the head?

A. I would suspect that it might do the reverse. There is one thing that is used in these preparations which might lead the patient to believe he was getting

some relief, menthol, which is a topical local anesthetic, a rather poor one, but it is to a degree, and this might temporarily lead a person to believe that he felt a little bit better, but at the same time menthol could be harmful to the mucous membrane and do him more injury than good.

Q. What is your opinion as to whether or not this product would be of value as an effective treatment for the relief of poor hearing, deafness, head noises or ear noises caused by excess fluid mucus?
A. I see no reason to think that it would be of use in the treatment of these conditions.

Q. What is your opinion as to whether or not this product would be of value as an effective treatment for the relief of poor hearing, deafness, head noises or ear noises caused by any other condition?
A. None whatsoever—it would be of no help.

Q. What is your opinion as to whether or not this product would have any beneficial effect on hearing losses or head noises or ear noises or catarrhal conditions of the head?
A. I do not believe it would be of any use whatsoever.[20]

Commission's medical witness, Dr. Fox, would be in agreement with Dr. Proctor, and further would testify in part as follows:

Q. Doctor, what does the word "catarrh" mean to you?
A. Medically, we do not use the word "catarrh" this is a term that is a lay term. It has no specific meaning. The older books on Pathology before we knew about allergies and before we knew about steriod problems, cortisone problems, before we knew about stress problems, the older books spoke of a catarrhal inflammation, meaning tissues that were swollen and looked irritated, but you could not find any infection in the sense of bacteria. You could not put your finger on what was wrong with you. They were not ulcerated, they were not infective—they were just swollen and

[20] Comm. Ex. No. 1, pages 22-25.

edematous and irritated. We have not used this term, except as a hang-over in one or two names which have stuck with us over the years, but we have not used this term in relation to disease of the ear, nose and throat, in about 30 years. It has been about 30 years since they, the books, contained it—we have tried to omit this and have gradually been able to do so. There is no specific Pathology. There is no specific cause. There is no specific disease. This is really a symptom complex when you do not know what else to call it, and you have no way of explaining it to the patient. As sometimes you say to an older patient, "what you have used to be called a catarrh."

Q. Doctor, using the term "catarrh" as meaning excess fluid mucus as it is used in the advertisement of the Elmo Company, can you tell us whether excess fluid mucus conditions of the head can cause ear noises and poor hearing?
A. They cannot.

Q. In your experience, doctor, what percentage of poor hearing and ear noises are caused solely by what is referred to in this advertisement in 1-A as "catarrhal conditions of the head"—which is excess fluid mucus?
A. I would say none, with the possible exception of the acute colds which for a few hours might block up the ears.

Q. Are older people likely to suffer from poor hearing and ear noises?
A. That is right. There is natural loss of hearing with every decade of life, starting at age 20, just as there is a loss of vision by age, and you wear bifocals as—with a natural loss of hearing.

Q. Doctor, is there anything new or unusual about the preparation or the devices contained in the Elmo Palliative Home Treatment?
A. They are very old preparations. All of the ingredients have been known, since, well, since the 1800's, some older than that. Many of these ingredients are listed in the Bible as being present. They are very old

preparations. There is nothing new. That is, about the preparations or their uses. There is no new knowledge about them that would make them any more effective than we thought they were 25 or 30 years ago when most of them were discarded.

Q. Have you used or tested the various preparations included in this treatment?
A. Under the name of "Elmo" preparations?

Q. That is correct.
A. No.

Q. Why not?
A. I would have no confidence or faith that they would have any effect from my knowledge of pharmacology and my knowledge of diseases of the ear, nose and throat. I would not subject a patient in this modern era to such drugs.

Q. Doctor, based on your scientific knowledge, your training, your research and experience, and bearing in mind the quantitative formulae and the directions for the use of the preparations and the devices comprising the Elmo Palliative Home Treatment, what is your opinion as to whether or not this product would be of value in curing catarrhal conditions of the head?
A. It would be worthless.

Q. What is your opinion as to whether or not this product would be of value in curing poor hearing caused by catarrhal conditions of the head?
A. It would be worthless.

Q. What is your opinion as to whether or not this product would be of value in curing ear noises caused by catarrhal conditions?
A. It is worthless.

Q. What is your opinion as to whether or not this product would be of value as a cure for poor hearing or ear noises caused by any other condition?
A. It's worthless.

Q. What is your opinion as to whether or not this product would be of value as an effective treatment for

the relief of catarrhal conditions of the head?
A. Ineffective.

Q. What is your opinion as to whether or not this product would be of value as an effective treatment for the relief of poor hearing, deafness, head noises or ear noises caused by catarrhal conditions of the head?
A. Ineffective.

Q. What is your opinion as to whether or not this product would be of value as an effective treatment for poor hearing, deafness, head noises or ear noises caused by any other conditions?
A. Ineffective.

Q. What is your opinion as to whether or not this product would have any beneficial effect on hearing loss or head noises or catarrhal conditions of the head?
A. It might have a harmful effect.

Q. Would it have any beneficial effect?
A. No, sir.[21]

Commission medical witness, Dr. Myer, also would be in agreement with the prior medical witnesses Dr. Proctor and Dr. Fox and further would testify in part as follows:

Q. Have you reviewed this complaint including the quantitative formulae and the directions for use for the various preparations comprising the Elmo Palliative Home Treatment?
A. Yes, sir.

Q. Are you familiar with the ingredient in the various formulae?
A. Yes, sir.

Q. Are you familiar with the devices included?
A. Yes, sir, I am.

Q. Is there anything new or unusual about any of these preparations or devices?
A. No, sir.

Q. Doctor, based on your scientific knowledge, training,

[21] Comm. Ex. No. 1, pages 33, 34, 40, 41, 48-50.

research and experience, and bearing in mind the quantitative formulae and the directions for use of the preparations and the devices comprising the Elmo Palliative Home Treatment, what is your opinion as to whether or not this product would be of value in curing catarrhal conditions of the head?

A. I would say that the treatments outlined in this pamphlet would not cure catarrhal conditions of the head.

Q. What is your opinion as to whether or not this product would be of value in curing poor hearing caused by catarrhal conditions of the head?

A. My opinion would be that the treatment outlined here would have very little effect on deafness or the cure of deafness.

Q. What is your opinion as to whether or not this product would have any value as a cure for poor hearing or ear noises caused by any other conditions?

A. In my opinion this would not cure any form of deafness.

Q. Or ear noises?

A. Or ear noises.

Q. What is your opinion as to whether or not this product would be of value as an effective treatment for the relief of catarrhal conditions of the head?

A. I have a very poor opinion of this product as a treatment for catarrhal conditions of the head.

Q. Could you be more explicit? Do you think it has any value for the relief of catarrhal conditions?

A. I think it has no value for the relief of catarrhal conditions.

Q. What is your opinion as to whether or not this product would be of value as an effective treatment for the relief of poor hearing, deafness, head noises or ear noises caused by catarrhal conditions of the head?

A. In my opinion this form of therapy outlined here would not cure the form of catarrhal deafness.

Q. My question, doctor, was directed to the relief of

poor hearing, ear noises, head noises or ear noises caused by catarrhal conditions.
A. I feel that it would not relieve these symptoms.

Q. What is your opinion as to whether or not this product would be of value as an effective treatment for the relief of these same symptoms caused by other conditions other than catarrhal conditions of the head?
A. I feel they would have no effect in relieving these conditions or symptoms or curing them.

Q. What is your opinion as to whether or not this product would have any beneficial effect upon hearing loss or head noises or ear noises or catarrhal conditions of the head?
A. In my opinion the product would not affect the deafness or head noises or cure catarrhal conditions of the head.

Q. My question, Doctor, was directed as to whether it would have any beneficial effect disregarding the cure for the moment.
A. As I mentioned before, the use of nasal irrigation gives some comfort to patients who have crusting in their nose and throat, and if their complaint, problem is with dryness or the presence of large crusts or discharge in their nose and throat by washing their nose with the nasal douche they could clear the products of infection from their nose and throat. But this action would not cure the condition or make any change in the symptomatology. It wouldn't actually do any more good than nose flooding or expelling the products of inflammation from the nose or throat.

Q. Doctor, do you use irrigation to relieve patients who have head noises or ear noises?
A. No, sir.

Q. Would you prescribe the Elmo Palliative Home Treatment for any of your patients suffering from poor hearing, deafness or ear noises?
A. No, sir, I wouldn't.[22]

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[22] Comm. Ex. No. 1, pages 51, 53-54, 55-58.

11. The professional qualifications and specialized medical experience of the witnesses [23] and the excerpts from their medical testimony set forth in foregoing finding number 10, considered together with the preceding findings herein numbered 5 and 6, show grounds to exist and sufficient reason to believe that the public interest requires and would best be served, by the setting aside in part of the consent settlement's findings as to the fact and the order to cease and desist in this proceeding and the undertaking of corrective action as provided in paragraph (f) of Rule V of the Rules of Practice incorporated in the said settlement.[24] This would be in accord with the February 11, 1965 holding of the Appellate Court in *The Elmo Division of Drive-X Company, Inc., et al* v. *Federal Trade Commission*, 348 F.2d 342, at 346, footnote 7 of the court's opinion.

In making the instant finding, full consideration has been given by the hearing examiner to the cross-examination of the foregoing medical witnesses by the respondent,[25] the medical text book exhibits of respondent,[26] the direct testimony, professional qualifications and medical experience of respondent's medical witnesses,[27] the lay user testimony [28] and the testimonial letters and other material contained in respondent's submitted exhibits.[29]

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[23] Comm. Ex. No. 1, pages 3-9, for Dr. Proctor; pages 10-14, for Dr. Fox; pages 15-20, for Dr. Myers.

[24] The provisions of this rule appear on page 1, footnote 1, supra.

[25] Resp. Ex. No. 1, pages 3-61, for Dr. Proctor; pages 62-88, for Dr. Fox, pages 89-116, for Dr. Myers.

[26] Resp. Ex. No. 2, pages 7a-g, 8a-f, 9a-g, 10a-g, 12a-c, 14a-c, 15a-b, 16a-d, 17a-e, 18a-d. With regard to the use of medical text books on the direct and cross-examination of medical witnesses or as exhibits, see the February 28, 1964, Commission opinions in Docket No. 8490, *Sinkram Incorporated, et al.*

[27] Resp. Ex. No. 1, pages 120-136, and Resp. Ex. No. 2, pages 4a-k, for Dr. Cattell; Resp. Ex. No. 1, pages 136, 136a-n, 137 and Resp. Ex. No. 2, pages 11a-c, for Dr. Calesnick; Resp. Ex. No. 1, pages 138, 138a-d, 139-140, and Resp. Ex. No. 2, pages 13a-b, for Dr. Cherken.

[28] Resp. Ex. No. 1, page 141, for Joseph P. McDonald, pages 142-143, for Edna Gildersleeve.

[29] Resp. Ex. No. 2, pages 2a-b, directions for use of the "Elmo Palliative Home Treatment"; pages 3a-c, 19a-z29, confidential report blanks and testimonal letters sent to respondent by lay users of its treatment.

12. Respondent's answer filed to the Commission's reopening order herein alleges its advertisements as revised conform to the order to cease and desist of the 1952 consent settlement and make no remedial claims beyond the affording of temporary relief from the described symptoms. Respondent's answer also denies that it has represented either, directly or by implication, that its drugs or devices will cure or constitute an effective treatment for poor hearing, ear and head noises and so-called catarrhal conditions of the head.

Respondent's proposed findings of fact are to the effect in brief, that respondent purchased its corporate predecessor in reliance on a negotiated final consent settlement containing findings as to the facts and an order to cease and desist allowing the advertising of the "Elmo Palliative Home Treatment" to represent to the purchasing public that its use would afford not in excess of temporary relief from the advertised symptoms described, and that respondent's advertising of the said treatment is confined to such a represented result and when used as directed the treatment will afford the represented result as advertised.

Preceding finding number 6, at pages 7-8, supra, would show that respondent's advertising of the "Elmo Palliative Home Treatment" and its follow-up sales literature since the consent settlement are susceptible of the understanding by the purchasing public that the represented result from its use is not so confined as respondent contends,[30] but would extend to representing [31] that respondent's treatment will have a beneficial effect on and cure or constitute an effective treatment for poor or lost hearing, ear and head noises, and so-called catarrhal conditions of the head.

Respondent's medical text book exhibits and the testimony of its medical witnesses submitted on the record of

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[30] See *Aronberg* v. *Federal Trade Commission*, 132 F. 2d 165, at 167-168, holding "The public is not learned in medical technology. . . . The term 'relief' is not of definite connotation or entirely free from ambiguity; in a common sense, it connotes permanent removal of organic or functional disturbances, as distinguished from allocation of discomfort."

[31] See *Aronberg* case, footnote 30 above, "a representation that a medicine is 'for' or a 'treatment for' a disorder is equivalent to labeling it 'as a cure or remedy'."

this hearing are directed towards respondent's contention that use of the "Elmo Palliative Home Treatment" will afford not in excess of temporary relief from the symptoms described in its advertising. In turn, the testimony of the medical witnesses as submitted by Commission counsel and set forth in preceding finding number 10, at pages 9-17, supra, is in agreement and unequivocal that the use of the "Elmo Palliative Home Treatment" not only would not afford temporary relief from its advertised described symptoms, but further, that the treatment will not have a beneficial effect on and cure or constitute an effective treatment for poor or lost hearing, ear and head noises, and so-called catarrhal conditions of the head.

Respondent's claimed reliance on the finality of a negotiated consent settlement disregards paragraph (f) of Rule V of the Rules of Practice incorporated in the settlement. Further, the purpose of the present hearing is not to determine whether respondent's advertising of the "Elmo Palliative Home Treatment" is in compliance with the findings as to the facts and the order to cease and desist of the consent settlement, but to ascertain whether grounds exist which, in the public interest, require that the consent settlement be set aside in whole or in part.[32]

Respondent would argue that in assessing the medical evidence of record in this hearing, little weight should be given to the medical testimony submitted by Commission counsel because, allegedly, the witnesses had demonstrated no familiarity with nor tested the preparations and devices in the "Elmo Palliative Home Treatment," and further, that substantial weight is to be given the testimony and the written testimonials of the satisfied lay user purchasers of the treatment submitted of record by counsel for respondent.

Respondent's first argument is answered, to the contrary, in *Feil* v. *Federal Trade Commission,* 285 F.2d 879 at 893:

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[32] Respondent is presently subject to a penalty upon failure to comply with the various other paragraphs of the existing consent settlement order to cease and desist not containing permissive qualifications. If the consent settlement be set aside in whole and the order to cease and desist vacated, this would relegate the entire matter back to the complaint of 1952.

"In the petitioners' argument much is made of the fact that the medical experts produced by the Commission had little knowledge of the device, knew it only by reputation, or had only seen it demonstrated at the trial. The answer is that given by this Court in a similar case where objection was voiced that experts were allowed to testify as to the efficacy of a medical preparation which they had never prescribed or the effect of which they had not observed in concrete cases: 'The witnesses were shown to possess wide knowledge in the field under inquiry. There is no good reason to suppose them incompetent to express an opinion as to the lack of therapeutic value of petitioner's preparation merely because they had had no personal experience with it in the treatment of the disease. Their general medical and pharmacological knowledge qualified them to testify'."

Respondent's second argument is also answered, to the contrary, in the *Feil* case above, at page 882, footnote 5, wherein it is stated: "Coincidentally, the petitioner in that case urged, as do the petitioners in this case, that the Commission should not have rejected the testimonials from satisfied customers. The answer of the court was: 'Further, it is sound to say that the fact that petitioner had satisfied customers is not a defense to Commission action for deceptive practices'."

Respondent would further contend that in contrast to the public interest necessary for the issuance of a complaint, more is required in the public interest to disturb an allegedly final Commission order accepting a consent settlement such as here. If this be so, the required public interest is clearly present.[33] One quarter of a million people have already paid respondent either the first asking price of $10 or the follow-up price of $7.35 for the "Elmo Palliative Home Treatment." Unless the 1952 consent settlement be set aside in part and corrective action undertaken consistent with the preceding findings as herein made, a considerable number of the purchasing public may further go unprotected and suffer substantial monetary loss in the

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[33] Compare, *Exposition Press, Inc.* v. *Federal Trade Commission*, 295 F. 2d 869, at 872-874.

payment for a treatment described on the record of this hearing, by qualified and experienced medical specialists, as worthless for the represented results advertised.

Conclusions

The foregoing findings of fact show grounds to exist and reason to believe the public interest requires that the 1952 consent settlement in this proceeding be set aside in part and corrective action undertaken as provided in paragraph (f) of Rule V of the Rules of Practice incorporated in the said settlement.

Recommendations

Based on the record in this hearing, which is herewith certified to the Commission, together with the foregoing findings of fact and conclusions, it is recommended that the 1952 consent settlement in this proceeding be ordered set aside in part; that the allegations of the complaint be amended; and that the notice in the complaint contain that form of order to cease and desist which the Commission has reason to believe should be issued if the facts are found to be as alleged in the complaint, as amended.

Respectfully submitted,

Eldon P. Schrup,
Hearing Examiner.

June 15, 1966

UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 18559

THE ELMO DIVISION OF DRIVE-X COMPANY, INC., ET AL., *Apellants,*

v.

PAUL RAND DIXON,
THE FEDERAL TRADE COMMISSION, ET AL., *Appellees.*

Appeal from the United States District Court for the District of Columbia

Decided February 11, 1965

[348 F.2d. 342]

Mr. Geo. Stephen Leonard for appellants. *Mr. Richard L. Hirshberg* also entered an appearance for appellants.

Mr. David Epstein, Assistant United States Attorney, with whom *Messrs. David C. Acheson,* United States Attorney, *Frank Q. Nebeker* and *Miss Sylvia A. Bacon,* Assistant United States Attorneys, were on the brief, for appellees. *Mr. Harold D. Rhynedance, Jr.* Attorney, Fedearal Trade Commission, also entered an appearance for appellees.

Before PRETTYMAN, *Senior Circuit Judge,* and FAHY and BURGER, *Circuit Judges.*

PER CURIAM: Appellant sought declaratory and injunctive relief to stop the Federal Trade Commission from continuing with a complaint proceeding on the ground that a consent decree in an earlier proceeding requires the Commission to proceed by way of reopening that case. The District Court dismissed for want of jurisdiction; we must accordingly assume, for the purposes of the appeal, the truth of facts well pleaded. They are essentially the following: that appellant at all revelant times advertised and sold proprietary medicines; that in 1952 the Commission and appellant's predecessor in interest entered into a consent settlement with respect to certain advertising

practices the Commission found objectionable; that the settlement of that complaint proceeding provided that it could be set aside "in whole or in part under the conditions and in the manner provided in paragraph (f) of Rule V of the Commission's Rules of Practice; that Rule V provided for a reopening procedure whereby the Commission could set aside the consent settlement or any severable part thereof on finding a change of law or fact or that the public interest so required, and could *thereafter* undertake corrective action by adversary proceedings under the original or a new complaint as to any acts or practices not prohibited by any remaining provisions of the settlement; that the Commission over appellant's objections has sidestepped the stipulated reopening procedure and instituted a new complaint dealing with substantially the same matters covered by the consent decree; that the Commission's actions have caused and will cause substantial prejudice to appellant in its business and reputation, would subject it to full scale trial twice upon the same charges and would constitute a continuing forfeiture of its property resulting in irreparable injury; that appellant has exhausted its administrative remedies, since no order has been issued by the Commission which is appealable directly to the Court of Appeals.[1]

We hold that this complaint states a claim for relief and that the action is within the subject-matter jurisdiction of the District Court.

Statutory provisions concerning review of agency action by the Courts of Appeals do not in and of themselves, as the dissent seems to imply, preclude District Court jurisdiction. *A. F. of L.* v. *NLRB*, 308 U.S. 401 (1940), makes this clear. There the Supreme Court held Wagner Act provisions for Court of Appeals review foreclosed appellate review of § 9(c) certifications except as incidental to review of orders restraining unfair labor practices. The

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[1] Compare American Drug Corp. v. FTC, 149 F. 2d 608 (8th Cir. 1945), remanded to the Commission, 160 F. 2d 103 (1947), holding that a Court of Appeals has jurisdiction to review an *order* of the FTC *setting aside* a consent order without the hearing contemplated by 15 U.S.C. § 45(b), discussed *infra*. Here, in contrast, the Commission has entered no order purporting to set aside the existing consent order. See also n.7 *infra*.

Court went on to point out that whether District Courts could "review" certification proceedings was another question entirely, a question which was later resolved in *Leedom* v. *Kyne*, 358 U.S. 184 (1958), discussed *infra*.

The question we must resolve under *A. F. of L.* v. *NLRB*, *supra*, is thus whether Congress intended to foreclose District Court jurisdiction in the present case, given that its provision for Court of Appeals review does not per se preclude all District Court jurisdiction. Absent any clear directive in the statute itself or in the legislative history, it would seem necessary to decide this question on principle and by analogy to previous cases.

So proceeding, we see no reason to bar District Court jurisdiction here, for relief in that court is appellant's only effective remedy, as we will demonstrate. The prospect of ultimate appellate review of any final order issuing out of the new complaint proceeding is not adequate. The type of procedural error appellant asserts is not of a kind which affects the Commission's substantive findings; no one suggests that the Commission's complaint procedure is *unreliable* as a fact-finding mechanism. The dissent concedes that the propriety of the Commission's choice of procedure is not per se unsuited for judicial review. Once the feasibility of review is admitted, our inquiry should be directed to the appropriate *time* for such review.

Appellant does not seek review of any substantive determination made by the Commission; on the contrary, appellant concedes the Commission's right initially to pass on the legality of appellant's practices. *Myers* v. *Bethlehem Shipbuilding Corp.*, 303 U.S. 41 (1938), is thus not in point. In *Myers*, the petitioner had sought an injunction against an NLRB hearing claiming the Board lacked jurisdiction because the employer's business did not affect interstate commerce. In order for the District Court to grant the relief petitioner sought it would have had to determine an issue allocated for initial determination to the agency. The Supreme Court observed that to allow the petitioner's suit would "in effect substitute the District Court for the Board as the tribunal to hear and determine what Congress declared the Board exclusively

should hear and determine in the first instance." *Id.* at 50. Appellant here, unlike the petitioner in *Myers*, objects not to the fact of the Commission's making an initial substantive determination but rather to the process by which it has chosen to do so. And there would seem to be no such basis here to defer to any *procedural* "expertise" the Commission may have as there was to defer to the Labor Board's ability to decide what "affects interstate commerce" in *Myers*.

We see no ground on which we can distinguish the present case from *B.F. Goodrich Co.* v. *FTC*, 93 U.S.App. D.C. 50, 208 F.2d 829 (1953), *appeal after remand*, 100 U.S.App.D.C. 58, 242 F.2d 31 (1957). That case sustained the jurisdiction of the District Court to enjoin enforcement of the Commission's Quantity-Limit Rule 203-1 on the ground that the Commission had promulgated the rule without first making the findings on which Congress had expressly conditioned its statutory grant of authority to make such rules.[2] *Cf. Leedom* v. *Kyne*, 101 U.S. App. D.C. 398, 249 F.2d 490 (1957), *aff'd.* 358 U.S. 184 (1958) (District Court has jurisdiction where Board violates express condition of its authority to determine appropriate bargaining units); *Skinner & Eddy Corp.* v. *United States*, 249 U.S. 557 (1919) (Brandeis, J.) (District Court has jurisdiction where ICC permits new rate filing without hearing required by statute).[3]

In *Goodrich, supra*, *Kyne, supra*, and *Skinner & Eddy, supra*, the agency's action violated express statutory conditions of its authority which were found to give rise to

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[2] The decision was not premised, as the dissent implies, on the unavailability of judicial review at a later stage. A Court of Appeals reviewing a cease and desist order invoking the Quantity-Limit Rule to negative a cost-justification defense presumably could consider the validity of that rule.

[3] *Skinner & Eddy* is especially pertinent, since the statute there provided that the Commission might allow the new filing only after a *hearing* had established *changed conditions*. The Supreme Court sustained District Court jurisdiction to enjoin the filing though the petitioner had not sought relief within the Commission, since the complaint alleged that the Commission had exceeded its powers and, like appellant's complaint here, made no claim that the Commission had erred in consideration of the merits of a substantive issue consigned to it for initial determination.

enforceable rights in the parties for whose protection they existed. In the present case, appellant's rights are not spelled out so explicitly in the statute itself. 15 U.S.C § 45(b) provides:

> . . . [T]he Commission may at any time, *after notice and opportunity for hearing, reopen* and alter, modify, or set aside, in whole or in part, any report or order made or issued by it under this section, whenever in the opinion of the Commission conditions of fact or of law have so changed as to require such action or if the public interest shall so require: *Provided however,* That the said person, partnership, or corporation may, within sixty days after service upon him or it of said report or order entered after such a reopening, obtain a review thereof in the appropriate court of appeals of the United States . . . .

(Initial emphasis added.) We need not decide whether this language in the abstract amounts to the kind of "plain statutory command" on which District Court jurisdiction was premised in *Leedom* v. *Kyne, supra.*[4] Here the parties themselves by the consent decree have put a construction upon the statute which renders its directive of such a nature. The Commission promulgated Rule V(f) to implement § 45(b), and entered a consent order incorporating that Rule.

We hold merely that the incorporation of Rule V(f) into the consent decree which is binding on appellant and is equally binding on the Commission gives rise to an enforceable right in appellant to require the Commission to abide by the Rule.

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[4] The Commission argues that since the statute says the Commission *"may"* reopen, no such mandatory language appears as supported District Court jurisdiction in *Kyne*. While not reaching the question of the sufficiency of the statutory language *alone* to support jurisdiction, we note in passing that the Commission's argument is not weighty. A provision that the Commission *"shall"* reopen would make no sense at all: reopening is meant to be discretionary with the Commission, and reopenings the exception rather than the rule. We think it more likely that the language means the Commission *may* reopen any order if it chooses, and if it does so, it *shall* proceed in the manner detailed in the statute.

In our view it is not controlling that the terms of Rule V(f) do not themselves appear in the statute; such terms do not lend themselves to the rigidities of a statute and would not likely be found in the statute; rather they implement the basic statutory scheme. It is the Commission, not Congress, which has the task of shaping the general statutory directive of § 45(b) into workable procedural rules consistent with the congressional intent. The Commission can best judge which procedures are feasible; statutory rules of practice might not be sufficiently flexible to adapt to changing needs. But where, as here, the Commission promulgates a Rule filling in the statute's interstices, as Congress contemplated, and incorporates such a Rule into a consent settlement, we see no reason to distinguish between such a Rule and the statutory jurisdictional predicates involved in *Goodrich, Kyne,* and *Skinner & Eddy.*

The District Court, then, has jurisdiction to entertain appellant's complaint. In answering the question whether that complaint states a claim for relief which will support an injuction we need not inquire whether the statutory language alone or taken together with the promulgation of the implementing Rule, would give rise to an enforceable right.[5] But the incorporation of that Rule into the consent order "vested" appellant with a right to a reopening hearing.

The Commission's authority to promulgate the Rule and to incorporate it into consent agreements is unquestioned; it cannot and does not assert that it may avoid the obligation it here undertook because of "incapacity." And of course the Commission is free to alter its Rules of Practice as it sees fit, provided it does not contravene the statute.[6] But it may not unilaterally obliterate a part of the consideration—indeed an important part—by which

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[5] Even when not commanded by statute, the institution by an agency of regulations governing procedure may prevent deviation from them as long as they remain in effect. *Cf.* Vitarelli v. Seaton, 359 U.S. 535 (1959).

[6] As noted *supra,* the present case does not present the questions whether § 45(b) *by itself* requires the type of hearing afforded under Rule V(f), and if so whether that section *itself* confers a right enforceable in a District Court action.

it secured appellant's assent to be bound by a cease and desist order.[7]

Appellant does not ask us for an injunction against an abuse of discretion. It contends rather that the Commission's duty to proceed against it, if at all, according to Rule V(f) was "ministerial." We agree. When the thrust of a *statutory* command addressed to a public official is unmistakable, his duty to comply with it is "ministerial." This we believe to be the essence of *Goodrich, Kyne,* and *Skinner & Eddy.*[8]

We have said that we can see no significant difference, in the context of this case, between the commands addressed by statute to the agency officials in those cases and the command of the Rule here adopted to implement §

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[7] The Rule V(f) procedure requires a determination that there has been a change of law or fact—or that there is some public interest consideration—which justifies setting aside a consent order. Only after a hearing on those preliminary issues is the order to be disturbed at all under the Rule, and only after there has been such a setting aside is the Commission free under the Rule to bring a new complaint proceeding against any practice not governed by such parts of the consent order as remain in force.

Section 45(b) itself provides for direct Court of Appeals review of the outcome of reopening hearings. Congress thus apparently sought to insure that new complaint proceedings would not be instituted concerning practices subject to existing consent orders unless the prospective respondents first had a chance for judicial review of the necessity for disturbing such orders. This is some evidence that Congress, at least, considers the finality of consent orders to be of more than trivial concern.

By failing to hold the hearing contemplated by the statute and by not entering an *order* setting aside the existing consent order, the Commission subverts the opportunity for Court of Appeals review given by the statute. See n. 1 *supra.*

[8] The Supreme Court long ago indicated that mandamus would lie in such a case:

> Unless . . . mandamus is to become practically valueless, and is to be refused even where a public officer is commanded to do a particular act by . . . a particular statute, . . . [the writ] should be granted. Every statute to some extent requires construction by the public officer whose duties may be defined therein. Such officer must read the law, and he must therefore . . . construe it. . . . But that does not necessarily . . . make the duty . . . anything other than a purely ministerial one.

Roberts v. United States, 176 U.S. 221, 231 (1900).

45(b) and written into the consent agreement. Of course, the Commission, and only it, had discretion whether to proceed at all against appellant in relation to the advertising practices which were the subject of the agreement. But once the discretionary decision to act was taken, the choice of procedure was prescribed by § 45(b) of the statute as implemented by the parties by incorporating the Commission's own Rule into the consent decree. In sum, given that the Rule was a term of the agreement, the duty to proceed according to its unambiguous provision was clear.[9]

Were this an action between private parties, appellant would be hard pressed to demonstrate absence of an adequate remedy at law and this would ordinarily render specific relief inappropriate. Here, however, the injury which appellant asserts is one for which any adequate legal remedy is very remote.[10]

Indiana & Michigan Elec. Co. v. *FPC*, 224 F. Supp. 166

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[9] See McKay v. Wahlenmaier, 96 U.S. App. D.C. 313, 226 F. 2d 35 (1955) (District Court has power to set aside "patently erroneous" application by Secretary of Interior of own regulation); Local Union No. 112, Int'l Union Allied Indus. Workers v. Rothman, 209 F. Supp. 295 (D.D.C. 1962) (District Court compels NLRB General Counsel to proceed to hearing at instance of charging party, since neither the statute nor the Board's regulations give General Counsel authority to settle complaints after issuance absent agreement of all parties).

[10] The need to insulate public officials from damage claims has led courts to find them imune from damage liability for failure to perform duties of the kind we find "ministerial" *for the purposes of this action*. The threat of liability in damages is likely to inhibit an official from "zealous and fearless administration of the law," Cooper v. O'Connor, 69 App. D.C. 100, 105, 99 F. 2d 135, 140, *cert. denied*, 305 U.S. 643 (1938), as the threat of an injunction is not. This immunity extends to erroneous construction and application of statutes. See, e.g., Taylor v. McGrath, 90 U.S. App. D.C. 201, 194 F. 2d 883 (1952). See generally Commercial State Bank of Roseville v. Gidney, 174 F. Supp. 770 (D.D.C. 1959), *aff'd*, 108 U.S. App. D.C. 37, 278 F. 2d 871 (1960); Davis, *Administrative Officers' Tort Liability*, 55 MICH. L. REV. 201 (1956).

Nor would appellant's likelihood of success be greater in a suit against the United States under the Tort Claims Act. Even if the official conduct here involved would be found *for the purposes of that Act* to be the violation of a ministerial duty rather than the irremediable abuse of a discretionary one, the Act excepts interference with contract rights—the essence of appellant's claim—from its purview. 28 U.S.C. § 2680(h).

(N.D. Ind. 1963), cited by the dissent to show the availability of other adequate relief to appellant, is inapposite. The premise of that case is that procedural errors committed by the Commission in the course of an otherwise lawful proceeding can be remedied by the grant of a new hearing by a Court of Appeals reviewing a final order if they appear to prejudice the reliability of the Commission's fact findings. And indeed the remand envisioned would be adequate to remedy the wrong claimed in the *Indiana* case—denial of a fair hearing. As we have pointed out above, however, such a remand would serve no purpose here, since appellant concedes the *reliability* of the Commission's complaint procedure. The gist of appellant's complaint is rather that the Commission may not institute any complaint proceeding against it in relation to matters covered by the consent order until the necessary preliminary findings have been made at a reopening hearing reviewable by a Court of Appeals. Given the nature of the injury claimed, an appellate court reviewing an order resulting from the new complaint proceeding can afford appellant no meaningful remedy.[11]

We hold that the unavailability of other adequate relief justifies the issuance of an injunction against the new complaint proceeding upon a proper showing. Appellant's complaint thus states a claim for relief which the District Court must entertain. That court on remand may of course explore any factual issues tendered concerning the identity of the practices subject to the consent order and those here proceeded against, and any effects on such practices which appellant's intervening change of corporate form may have had.[12] We have not dealt with these matters,

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[11] Even if an appellate court could devise effective relief at this stage, the litigant who has failed first to seek relief in a District Court runs the risk of being estopped to complain under the principle of St. Regis Paper Co. v. United States, 368 U.S. 208 (1962).

[12] We do not think the procedure now directed by this court, *i.e.*, a remand to the District Court for limited purposes, is so "cumbersome" that it should divert us from requiring the Commission to adhere to its own Rules and its own explicit consent decree. Procedural safeguards are often cumbersome in a relative sense, but short cuts and cutting of procedural corners by a regulatory body are pregnant with mischief.

urged upon us by the Commission, since they were not raised in the District Court, which found only that it lacked jurisdiction to proceed. If it shall appear that the practices now complained of by the Commission vary significantly from those governed by the consent settlement, appellant cannot object to a new complaint directed at new conduct.

Reversed and remanded for further proceedings.

FAHY, *Circuit Judge, dissenting*: I agree with the District Court in its dismissal of the complaint, so I respectfully dissent from this court's reversal and remand.

The complaint in the District Court of Elmo Division of Drixe-X Co., Inc., prayed the court to enjoin the Federal Trade Commission and its members from proceeding further against Elmo by means of a Federal Trade Commission complaint rather than by procedures available under Commission rules of practice for reopening for possible amendment a previous consent decree entered into between Elmo and the Commission.

The Federal Trade Act provides for judicial review of orders of the Commission, entered in complaint proceedings, by the Courts of Appeals of the United States, 38 Stat. 719 (1914), 15 U.S.C. § 45, particularly §§ 45(c) and (d) (1958). This method of review was specially designed by Congress and necessarily enables the Commission, without prior judicial intervention, to pursue its own administrative procedures which might lead to an order. This Congressional plan cannot be preserved if the District Courts may exercise their general equity jurisdiction to forestall or interrupt the statutory process.

Elmo claims, as above indicated, that it is injured by the Commission having erroneously issued a new complaint, instead of reopening a previous consent decree. But a claim in the District Court that the Commission is using erroneous procedure in a particular case, and is thus subjecting a party to the expense and inconvenience of litigation, does not vest jurisdiction in the court in contravention of normal statutory review provisions. *Myers* v. *Bethlehem Shipbuilding Corp.*, 303 U.S. 41, 51 (1938). The question is not

whether a procedural error may have occurred at the Commission level, as to which I express no opinion, but rather how and when an alleged error of the Commission is to be judicially considered. Congress has provided the method in the Act itself, thus precluding it to a District Court exercising equity jurisdiction. *Cf. Whitney Nat'l Bank* v. *Bank of New Orleans,* —— U.S. ——, decided January 19, 1965.

The court's reliance on *Leedom* v. *Kyne,* 358 U.S. 184 (1958), a case of very limited scope, I think is unfounded. There the Labor Board had violated the statute in the course of a proceeding resulting in a union certification, ordinarily non-reviewable under the Labor Act. Jurisdiction in the District Court was sustained to enjoin the Board from depriving some of the affected employees of a substantive right clearly granted to them by statute. Unless the District Court had intervened the deprivation could not have been reviewed at the instance of the employees whose rights were obliterated by the Board action, a situation not comparable to that here present. And in *B. F. Goodrich Co.* v. *FTC,* 93 U.S. App. D.C. 50, 208 F.2d 829 (1953), appeal after remand, 100 U.S. App. D.C. 58, 242 F.2d 31 (1957), the Commission order was in the form of a rule of general application not subject to the ordinary judicial review procedures of the Federal Trade Act. In both *Goodrich* and *Leedom* v. *Kyne* the agency had taken action which had a direct impact upon the plaintiffs. In the former the companies had been subjected to a Commission order affecting their business operations, compliance or noncompliance with which order caused immediate consequences to such operations without further agency action. 93 U.S. App. D.C. 50, 208 F.2d 829.[1] And in *Leedom* v. *Kyne,* as I have said, the Board action had brought about the deprivation of a substantive statutory right. In neither case was the challenged action reviewable, by those affected, under the specially designed statutory review procedures. In con-

[1] In *Skinner & Eddy Corp.* v. *United States,* 249 U.S. 557 (1919), relied upon by the court, an order of the Interstate Commerce Commission, claimed to be in excess of its statutory authority, with immediate impact upon the plaintiffs, was involved. No order of this character has been issued by the Commission in our case.

trast, no action of like impact had been taken by the Commission in this case. Only a Commission proceeding on a complaint had been initiated. Should it eventuate in a Commission order adverse to appellant the order would be reviewable by a Circuit Court of Appeals, for procedural as well as substantive error. In the meantime the possible injury or impact upon appellant is only that which *Myers, supra,* clearly holds insufficient as a basis for departing from the statutory procedures.[2]

The mistake of my brethren, I respectfully suggest, is emphasized by the concluding paragraph of the opinion which directs the District Court to compare the practices now complained of with those involved in the consent order. If the former differ significantly from the latter, the court concludes, the new complaint may issue. Surely, as it seems to me, this is a very cumbersome as well as a mistaken substitute for the statutory provisions for review of such order, if any, as the Commission may issue in its complaint proceedings.

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[2] *Mandamus* by way of 28 U.S.C. § 1361 is an extraordinary remedy which invokes the equity powers of a district court. Even if the Commission's action could be classified as ministerial, *mandamus* in this case is barred because Congress has provided an adequate remedy. *Cf. Indiana & Michigan Elec. Co.* v. *FPC,* 224 F. Supp. 166 (N.D. Ind. 1963), and cases cited therein.

PETITIONER'S PROPOSED FINDINGS WITH AGENCY RECORD REFERENCES

11. The Elmo Palliative Home Treatment has been advertised and sold by respondent's predecessor and respondent for approximately thirty years. Prior to June 10, 1952 respondent's predecessor advertised these medicines for sale in a manner conceded to have represented, directly or by implication, that the use thereof would cure or constitute an effective treatment for deafness, impaired hearing, and ear and head noises due to catarrh. The Commission, alleging that such representations were misleading in material respects, issued a complaint with respect thereto on February 28, 1952. Respondent's predecessor thereupon negotiated with the Commission staff a cease and desist order, to be issued on consent without a hearing and which would limit further claims of the therapeutic effects of such preparations to the temporary relief of deafness or impaired hearing and ear or head noises resulting from catarrhal conditions. On June 10, 1952, the Commission, finding the entry of such a consent decree to be in accord with the public interest, approved the same and issued its cease and desist order. In so acting, it does not now appear that either the Commission staff or the Commission itself in 1952 had caused to be procured for the purpose any medical reports or other record information regarding the therapeutic efficacy of the preparations concerned.

> R1-116f*, "approximately 30 years"; 48 F.T.C. 1379, 1389-90; Order 1393-4; Tr. (2/18) 28, 29, "... the Commission acted at that time with no medical reports in the files ... there was nothing existent on which they acted ... MR. CHARLTON: Correct."

12. Subsequently respondent's predecessor revised its advertising for the drugs in question to conform to the requirements of the order and secured opinions of counsel that such revised advertising was in fact in conformity

* Citations are to Commission's Exhibit No. 1: "C1- "; and Respondent's Exhibits Nos. 1 and 2: "R1- ", "R2- ".

therewith. Nine years later, in September 1961, respondent purchased the assets and business of respondent's predecessor in advertising and marketing the Elmo Palliative Home Treatment, so acting in reliance on the apparent finality of the earlier decree and the legal opinions as to the compliance with such decree of the revised advertising practices of respondent's predecessor. Since September 1961 respondent has made no substantial changes in such advertising.

R1-116a-d, compliance review—L. W. Ramsey Advertising Agency, attorneys Bradshaw and Arnold, Fortas and Porter; "We made no changes."

13. To each person responding to one of the said advertisements, respondent sends a questionnaire to determine whether the inquirer's condition is catarrhal in nature, pointing out therein that the preparations will be of no value in infective or other non-catarrhal conditions and should not be used in lieu of professional attention. Approximately one-third of all orders subsequently received by respondent are not filled by them due to replies made in such questionnaire which indicate non-catarrhal conditions for which the Elmo Palliative Home Treatment would concedely be of no benefit. As to the balance of the orders received, respondent's medicines are then forwarded on a thirty-day trial basis, no amount being payable therefor unless the user has secured and will report receiving symptomatic relief thereby.

Questionnaire C1-59; sent to all, R1-116e; warnings, C1-60; one-third declined, R1-1, 2; trial basis, C1-59; R1-116e, f.

14. At any hearing involving the substantive issue of whether the therapeutic effectiveness of the Elmo medicines extends to the symptomatic relief which the 1952 order permits it to advertise, respondent would be able to produce thereat substantial pharmacologic and medical evidence to show that

(a) these are standardized pharmaceutical products, the formulas for which were prescribed and compounded by the founders of respondent's predecessor, two practicing ear, nose and throat physicians. The formulas are typical of the prescriptive practice of this branch of the medical profession for catarrhal conditions at the time of their formulation and are still commonly used in proprietary medicines, although to a lesser extent in medical practice, having been largely displaced in such practice by stronger, prescription-only pharmaceuticals.

"... formulated by the two Dr. Coffee's ... practicing ear, eye, nose and throat men." R1-118; one hundred years old, *Proctor,* R1-57, "familiar ingredients," R1-7; *Fox* has used these ingredients, in common use by doctors in the '30's, R1-71, "old fashioned remedies," R1-87; *Myers* has used, "common, routine," R1-93, 94, 116; biblical in origin, *Fox,* R1-68; *Cattell* has used, R1-126, were "common prescription items," R1-126, 127, ingredients are drugs which have known pharmacological properties, R1-124, 135; *Calesnick,* R1-137; *Cherken,* R1-137. Still in limited use today; *Myers,* R1-116; *Cattell,* R1-126, 135; *Calesnick,* R1-137; *Cherken,* R1-138; common in proprietary items; some use in prescriptions, *Calesnick,* R1-137; ingredients listed, *Boise,* R2-10C-G under heading "Useful Older Medications."

(b) The ingredients of the Elmo preparations have been and are still accepted today by pharmacological and medical authorities as having the properties which would accomplish the types of symptomatic relief described in respondent's advertising.

(A) *Phenol*: Anesthetic, *Myers,* R1-107; and antiseptic, *Proctor,* R1-32; *Krantz,* R2-8-C; reducing pain when used in ear drops, *Boise,* R2-10-C; prevents bacterial growth, useful on mucous membranes and gargles and lotions, *Sollmann,* R2-9-F; local anesthetic, *Goodman,* R2-7-F. Listed by *Boise,* R2-10-F.

(B) *Thymol*: Anti-fungal, *Fox,* R1-77, 65; *Krantz,* R2-

8-D; bacteriostatic and anesthetic, *Goodman,* R2-7-F; *Krantz,* R2-8-D; useful as antiseptic gargle, *Sollmann,* R2-9-C; listed by *Boise* and "Physician's Desk Reference," R2-10-F, 12-B.

(C) *Menthol*: Local anesthetic, relieves pain, cooling *Fox,* R1-63, 65; *Proctor,* R1-41; *Sollman,* R2-9-B; listed by *Boise* and *Stevens,* R2-10-F, 15-B and "Physician's Desk Reference," R2-12-B.

(D) *Potassium Iodide*: Liquifies mucous, *Goodman,* R2-7-F; *Sollmann,* R2-9-F; *Stevens,* R2-15-B; reduces inflammation, *Goodman,* R2-7-E; listed in P.D.R., R2-12.

(E) *Chloroform* (external use): Counter-irritant and liniment, *Krantz,* R2-8-C; P.D.R., R2-12.

(F) *Zinc Sulphate*: Astringent, reducing swelling of mucous membrance, *Proctor,* R1-37; *Fox,* R1-65; 71-2; used in nasal spray to shrink mucous membranes, *Goodman,* R2-7-G; used for catarrhal conditions, *Sollmann,* R2-9-G; P.D.R.

(G) *Boric Acid*: Antiseptic and astringent, *Sollman,* R2-9-F. *Proctor* stated it has no value but that some doctors use it, R1-40. Nevertheless, *Boise* of the Mayo Clinic lists it as an ingredient of his recommended "liquor antisepticus," R2-10-C; see also current uses in P.D.R., R2-12.

(H) *Eucalyptus* (oil of eucalyptus): Anesthetic, *Fox,* R1-62, 63; *Myers,* R2-106, rubefacient, R1-96; like other volatile oils, counterirritants, and bases of liniments and rubefacients, *Sollmann,* R2-9-B; for which purpose used in nasal sprays, *Goodman,* R2-7-F; or inhalant, *Boise,* R2-10-F; *Sollmann,* R2-9-B. *Sollman* also gives pine needle oil as an inhalant, R2-9-B. *Krantz* lists oil of mustard as a counterirritant, oil of peppermint as antibacteriostatic, useful in mouth washes, R2-8-B; *Stevens,* R2-15-B.

(I) *Salicylates*: (1) *Methyl Salicylate* (oil of wintergreen): rubefacient, *Fox,* R1-62, 63, 81; rubefacient and anesthetic, *Myers,* R1-96, 106; *Krantz,* R2-8-B;

anesthetic, *Fox,* R1-81; anti-inflammation absorbed through skin, *Krantz,* R2-8-C, E; *Sollmann,* R2-9-D; for use in ointment, *Goodman,* R2-7-B; as gargle, *Boise,* R2-10-C, F; P.D.R. (2) *Sodium Salicylate*: mild anesthetic, *Fox,* R1-64; *Myers,* R1-106; predecessor of aspirin, *Fox,* R1-64; milder than aspirin, absorbed through mucous membrane, *Sollman,* R2-9-D; P.D.R. (3) *Salicylic Acid:* Anesthetic and keratolytic, *Fox,* R1-65. (4) The *salicylic family* are analgesic and bacteriostatic, *Goodman,* R2-7-A; *Krantz,* R2-8-E.

(J) *Sodium Benzoate*: Astringent, *Myers,* R1-105, 6; expectorant, similar to salicylic acid, *Sollmann,* R2-9-E; preservative, *Fox,* R1-64.

(K) *Sodium Borate*: Cleansing agent, *Fox,* R1-63, dissolves mucous, *Sollmann,* R2-9-F.

(L) *Silver Nitrate*: mild astringent, *Fox,* R1-79.

(M) *Capsicum*: Rubefacient, *Fox,* R1-63; used in liniments, P.D.R.

(c) The pharmacologic properties of the ingredients used in the Elmo preparations continue in the particular combinations used. The symptomatic relief for which these ingredients were prescribed in the older medical practice is still given by their use today. The use of the Elmo preparations as directed would consequently grant the symptomatic relief characteristic of the recognized properties of their components.

(A) On their ingredients Elmo products would relieve the advertised symptoms and will continue to give the symptomatic relief these drugs gave when they were common prescription items, *Cattell,* R1-135; *Cherken,* R1-140. Such preparations were prescribed for catarrhal conditions by *Fox,* R1-68, 71; *Myers,* R1-93; *Cattell,* R1-135; *Cherken,* R1-139—in fact every medical witness except *Proctor.* They were so used because they were the best that the medical profession had at the time, *Cattell,* R1-135; but are still regarded as useful for the same purpose by medical practitioners, *Calesnick,* R1-137; by the standard pharmacological

and medical texts, R2-7, 8, 9 and 10; have a continued if limited prescriptive use today, (Par. (a) *supra*), are in current common use in proprietary medicines, P.D.R., *Calesnick,* R1-137. *Cherken* and *Calesnick* agree with *Boise* as to value of present use, R1-138c, R1-136f, i. As used today in the Elmo preparations, these ingredients would relieve the user in the form of liquefying and carrying away the excess mucous in his nose and throat, *Cattell,* R1-135; would help to open the Eustachian tubes, *Cherken,* R1-140; and, in fact, would give the same relief today they have given in prior times, *Cattell,* R1-135-6; *Cherken,* R1-140. As to the form of the medications, the one writer agreed on by all witnesses as being a principal authority, *Dr. Boise* of the Mayo Clinic, recommended similar preparations as useful older medications in nose drops, R2-10-B; ear drops, R2-10-C; gargle, R2-10-F; nasal irrigation, R2-10-E; and the much disputed use of vaseline (petrolatum) as a medium to carry these medications, R2-10-B. Nose drops are commonly used, *Calesnick,* R1-136g; *DeWeese,* R2-18-B. *Boise* recommended gargling, specifically with Dobell's and Seiler's solutions having similar ingredients, R2-10-F, concurred in by *Calesnick,* R1-136i, *Proctor* (using salicylates) R1-60, and to relieve inflammation by *Myers,* R1-110. Although *Fox* stated that the use of such a gargle was bad, R1-69, *Myers* prescribed them, R1-95, as did *Boise,* R2-10-F. *Myers* said this would give "comfort to patients," R1-93, is recommended by *Boise,* R2-10-E, and stated to be in medical use today, *Cattell,* R1-127; *Calesnick,* R1-136; *Ballenger,* R2-16-C.

(B) As to the debated value of otomassage, *Fox* regarded the Elmo ear vibrator as essentially the same as a Delstanche apparatus, R1-88; *Proctor* identified it as such and said it might work efficiently, R1-44; *Myers* stated that otomassage was used today, R1-95. As to tympanic inflation (Valsalva's method), also covered in the Elmo directions, *Proctor* considered it to have value, R1-43; *Fox* thought it could help but could be overdone, R1-86; *Myers* said it would unclog

the Eustachian tube, R1-109. It is recommended in *Ballenger*, R2-16-B, and *Jackson*, R2-17-D.

(C) Neither *Proctor*, *Fox* nor *Myers* held consistently to their generalized proposition that the use of the Elmo preparations would be ineffective for their advertised purpose. *Proctor* stated that he lacked knowledge of these ingredients, R1-28, 30, 33, 34, 36, 37, 56, 60; and *Fox* limited his disagreement that they were not "more effective than we thought they were 25 or 30 years ago," R1-68. *Dr. Myers* said the value of this type of therapy was a subject of disagreement between doctors, particularly as between general practitioners and ear, nose and throat specialists, R1-113-115.

(D) Affirmatively, the preparations as a whole would give the advertised symptomatic relief: *Cattell*, R1-135; *Calesnick*, R1-137; *Cherken*, R1-140.

No. 1 (Ear Drops) would give sense of warmth and anesthetize, *Fox*, R1-69, 82; a sense of warmth and bring blood to the surface, *Myers*, R1-96; be a counterirritant, antiseptic and emollient and would tend to increase circulation, *Cattell*, R1-126, 127. *Boise* states that ear drops relieve earache in middle ear diseases, R2-10-C. "All very commonly used compounds," *Cattell*, R1-126.

No. 2 (Nasal Cleaner), most commonly used ingredients in the past and in some use today, "would tend to liquefy and wash out mucous" from the nose and throat, *Cattell*, R1-127; would "give some comfort . . . expelling the products of inflammation from nose and throat," *Myers*, R1-93, 94.

No. 3 (Gargle). Common ingredients of gargles and would have the anesthetic and antiseptic effects to be expected from these ingredients, *Cattell*, R1-128. (Although "gargles don't work." *Fox*, R1-69, *Proctor* prescribes aspirin gargle, saying only as to the equivalent salicylic acid in the Elmo formulations that he was "not sure it would be *very* effective." R1-60) Could relieve inflammation in throat, *Myers*, R1-110.

No. 4 (Inhalant). "Pleasant and anesthetic," would make throat feel open, *Fox,* R1-69, 70; common inhalant ingredients with local anesthetic and antiseptic effect, *Cattell,* R1-128; would increase secretion and loosen and flow mucous and bring blood supply to part, R1-130, and reach pharyngeal opening of Eustachian tube, R1-131.

No. 5 (Massage Ointment). Counterirritant, *Cattell,* R1-131, relief arises through referred pain concept, R1-130, 132.

No. 6 (Nasal Ointment). Common formulation having an antiseptic, anesthetic and rubefacient effect tending to increase circulation in the nose, *Cattell,* R1-133.

15. At any such hearing, respondent could also produce oral and written testimony by numerous users of the Elmo treatment that the type of symptomatic relief described in the Elmo advertising, authorized by the 1952 decree, and predicted as the anticipated result of the use of these medicines by the medical and pharmacological evidence, was in fact experienced by them as a result of the use of the Elmo treatment.

Direct testimony of relief after 20 years from tinnitus and hearing loss accompanying catarrhal conditions, *McDonald,* R1-141; after 1½ years, *Gildersleeve,* R1-143. Catarrhal type symptomology and no medical reason why these and other persons could not have secured the relief they claimed from using Elmo, *Cherken,* R1-138d, *Calesnick,* R1-136n. Three-fifths of the persons using Elmo report receiving same relief, *Sandahl,* R1-116f. About 250,000 persons have reported relief in 30 years, id. R1-116f; same specific types of relief are being reported today, R2-3a, b, R2-19A-Z30; and no person has ever reported being harmed by the use of the Elmo treatment, R1-119.

Federal Trade Commission Act, § 5(b) [15 U.S.C. § 45(b)]

Proceeding by Commission; modifying and setting aside orders

(b) Whenever the Commission shall have reason to believe that any such person, partnership, or corporation has been or is using any unfair method of competition or unfair or deceptive act or practice in commerce, and if it shall appear to the Commission that a proceeding by it in respect thereof would be to the interest of the public, it shall issue and serve upon such person, partnership, or corporation a complaint stating its charges in that respect and containing a notice of a hearing upon a day and at a place therein fixed at least thirty days after the service of said complaint. The person, partnership, or corporation so complained of shall have the right to appear at the place and time so fixed and show cause why an order should not be entered by the Commission requiring such person, partnership, or corporation to cease and desist from the violation of the law so charged in said complaint. Any person, partnership, or corporation may make application, and upon good cause shown may be allowed by the Commission to intervene and appear in said proceeding by counsel or in person. The testimony in any such proceeding shall be reduced to writing and filed in the office of the Commission. If upon such hearing the Commission shall be of the opinion that the method of competition or the act or practice in question is prohibited by sections 41-46 and 47-58 of this title, it shall make a report in writing in which it shall state its findings as to the facts and shall issue and cause to be served on such person, partnership, or corporation an order requiring such person, partnership, or corporation to cease and desist from using such method of competition or such act or practice. Until the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time, or, if a petition for review has been filed within such time then until the record in the proceeding has been filed in a court of appeals of the United States, as hereinafter provided, the Commission may at any time, upon such notice and in such

manner as it shall deem proper, modify or set aside, in whole or in part, any report or any order made or issued by it under this section. After the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time, the Commission may at any time, after notice and opportunity for hearing, reopen and alter, modify, or set aside, in whole or in part, any report or order made or issued by it under this section, whenever in the opinion of the Commission conditions of fact or of law have so changed as to require such action or if the public interest shall so require: *Provided, however,* That the said person, partnership, or corporation may, within sixty days after service upon him or it of said report or order entered after such a reopening, obtain a review thereof in the appropriate court of appeals of the United States, in the manner provided in subsection (c) of this section.

(4201-Q)